CLAIMS

What is claimed is:

1. A method of treating fibromyalgia in a mammal comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of the formula I

$$\begin{array}{c|c} R_3 & R_2 \\ & | \\ H_2N - CH - C - CH_2 - CO_2H \\ & | \\ R_1 \end{array}$$

or a pharmaceutically acceptable salt thereof, wherein:

R₁ is a straight or branched unsubstituted alkyl of from 1 to 5 carbon atoms, unsubstituted phenyl, or unsubstituted cycloalkyl of from 3 to 6 carbon atoms;

R₂ is hydrogen or methyl; and

R₃ is hydrogen, methyl, or carboxyl.

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2. A method of treating a disorder or condition selected from the group consisting of sleep disorders such as insomnia (e.g., primary insomnia including psychophysiological and idiopathic insomnia, secondary insomnia including insomnia secondary to restless legs syndrome, Parkinson's disease or another chronic disorder, and transient insomnia), somnambulism, sleep deprivation, REM sleep disorders, sleep apnea, hypersomnia, parasomnias, sleep-wake cycle disorders, jet lag, narcolepsy, sleep disorders associated with shift work or irregular work schedules, deficient sleep quality due to a decrease in slow wave sleep caused by medications or other sources, and other sleep disorders in a mammal, comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of the formula I

or a pharmaceutically acceptable salt thereof, wherein:

R₁ is a straight or branched unsubstituted alkyl of from 1 to 6 carbon atoms, unsubstituted phenyl, or unsubstituted cycloalkyl of from 3 to 6 carbon atoms;

R₂ is hydrogen or methyl; and

R₃ is hydrogen, methyl, or carboxyl.

3. A method of increasing slow wave sleep in a human subject comprising administering to a human subject in need of such treatment an amount of a compound of the formula I

$$H_2N$$
— CH — C — CH_2 — CO_2H

or a pharmaceutically acceptable salt thereof, wherein:

R₁ is a straight or branched unsubstituted alkyl of from 1 to 5 carbon atoms, unsubstituted phenyl, or unsubstituted cycloalkyl of from 3 to 6 carbon atoms:

R₂ is hydrogen or methyl; and

R₃ is hydrogen, methyl, or carboxyl;

That is effective in increasing slow wave sleep.

4. A method of increasing secretion of a human growth hormone in a human subject comprising administering to a human subject in need of such treatment an amount of a compound of the formula I

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$$H_2N$$
— CH — C — CH_2 — CO_2H

or a pharmaceutically acceptable salt thereof, wherein:

R₁ is a straight or branched unsubstituted alkyl of from 1 to 5 carbon atoms, unsubstituted phenyl, or unsubstituted cycloalkyl of from 3 to 6 carbon atoms;

R₂ is hydrogen or methyl; and

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R₃ is hydrogen, methyl, or carboxyl;

that is effective in increasing secretion of a human growth hormone.

5. A method of treating irritable bowel syndrome in a mammal, preferably a human, comprising administering to a human subject in need of such treatment a therapeutically effective amount of a compound of the formula I

or a pharmaceutically acceptable salt thereof, wherein:

R₁ is a straight or branched unsubstituted alkyl of from 1 to 5 carbon atoms, unsubstituted phenyl, or unsubstituted cycloalkyl of from 3 to 6 carbon atoms;

R₂ is hydrogen or methyl; and

- 20 R₃ is hydrogen, methyl, or carboxyl.
 - 6. A method of treating a disorder or condition selected from the group consisting of panic disorder with or without agoraphobia, agoraphobia without history of panic disorder, specific phobias, social

anxiety disorder, social phobia, obsessive-compulsive disorder, and stress disorders including post-traumatic stress disorder and acute stress disorder in a mammal, comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of the formula I

$$H_2N$$
— CH — C — CH_2 — CO_2H

or a pharmaceutically acceptable salt thereof, wherein:

R₁ is a straight or branched unsubstituted alkyl of from 1 to 5 carbon atoms, unsubstituted phenyl, or unsubstituted cycloalkyl of from 3 to 6 carbon atoms;

R2 is hydrogen or methyl; and

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R₃ is hydrogen, methyl, or carboxyl.

- 7. A method of treating a disorder or condition selected from the group consisting of panic disorder with or without agoraphobia, agoraphobia without history of panic disorder, specific phobias, social anxiety disorder, social phobia, obsessive-compulsive disorder, and stress disorders including post-traumatic stress disorder and acute stress disorder in a mammal, comprising administering to a mammal in need of such treatment:
 - (a) a compound of the formula I

$$H_2N$$
— CH — C — CH_2 — CO_2H

or a pharmaceutically acceptable salt thereof, wherein:

R₁ is a straight or branched unsubstituted alkyl of from 1 to 5 carbon atoms, unsubstituted phenyl, or unsubstituted cycloalkyl of from 3 to 6 carbon atoms;

R₂ is hydrogen or methyl; and

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R₃ is hydrogen, methyl, or carboxyl. compound of the formula I, or a pharmaceutically acceptable salt thereof; and

(b) another compound that is an antidepressant or an antianxiety agent, or a pharmaceutically acceptable salt thereof;

wherein the amounts of the active agents "a" and "b" are chosen so as to render the combination therapeutically effective.

- 8. A method according to claim 7, wherein the disorder or condition being treated is post traumatic stress disorder.
- 9. A method according to claim 7, wherein the disorder or condition being treated is social phobia or social anxiety disorder.
 - 10. A method of treating two or more disorders or conditions, each of which is independently selected from the group consisting of irritable bowel syndrome, fibromyalgia, neuropathic pain, sleep disorders such as insomnia (e.g., primary insomnia including psychophysiological and idiopathic insomnia, secondary insomnia including insomnia secondary to restless legs syndrome, Parkinson's disease or another chronic disorder, and transient insomnia), somnambulism, sleep deprivation, REM sleep disorders, sleep apnea, hypersomnia, parasomnias, sleep-wake cycle disorders, jet lag, narcolepsy, sleep disorders associated with shift work or irregular work schedules, deficient sleep quality due to a decrease in slow wave sleep caused by medications or other sources, other sleep disorders, panic disorder with or without agoraphobia, agoraphobia without history of panic disorder, specific phobias, social anxiety disorder, social phobia, obsessive-compulsive disorder, and stress disorders including posttraumatic stress disorder and acute stress disorder in a mammal,

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comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of the formula I

$$H_2N$$
— CH — C — CH_2 — CO_2H

or a pharmaceutically acceptable salt thereof, wherein:

R₁ is a straight or branched unsubstituted alkyl of from 1 to 5 carbon atoms, unsubstituted phenyl, or unsubstituted cycloalkyl of from 3 to 6 carbon atoms;

R₂ is hydrogen or methyl; and

R₃ is hydrogen, methyl, or carboxyl.

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11. A method according to claim 1 wherein a compound of the formula I, or a pharmaceutically acceptable salt thereof, is administered to a human for the treatment of fibromyalgia and a concomitant disorder or condition selected from panic disorder, irritable bowel syndrome, functional abdominal pain, neuropathic pain, major depressive disorder and dysthymia.

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12. A method according to claim 1 wherein a compound of the formula I, or a pharmaceutically acceptable salt thereof, is administered to a human for the treatment of fibromyalgia and a concomitant somatoform disorder selected from somatization disorder, conversion disorder, body dysmorphic disorder, hypochondriasis, somatoform pain disorder, undifferentiated somatoform disorder and somatoform disorder not otherwise specified.

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13. A method of increasing slow wave sleep in a human subject being treated with an active pharmaceutical agent that decreases slow wave sleep comprising administering to such human subject a therapeutically effective amount of a compound of the formula I or a pharmaceutically acceptable salt thereof.

- 14. A method according to claim 14 wherein the active pharmaceutical agent that decreases slow wave sleep is morphine.
- 15. A method of increasing slow wave sleep in a human subject comprising administering to a human subject in need of such treatment:
- (a) a compound of the formula I or a pharmaceutically acceptable salt thereof; and
- (b) a human growth hormone or human growth hormone secretagogue, or a pharmaceutically acceptable salt thereof;

wherein the amounts of the active agents "a" and "b" are chosen so as to render the combination effective in increasing slow wave sleep.

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16. A method of increasing slow wave sleep in a human subject being treated with an active pharmaceutical agent that decreases slow wave sleep comprising administering to a human subject in need of such treatment:

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- (a) a compound of the formula I or a pharmaceutically acceptable salt thereof; and
- (b) a human growth hormone or human growth hormone secretagogue, or a pharmaceutically acceptable salt thereof;

wherein the amounts of the active agents "a" and "b" are chosen so as to render the combination effective in increasing slow wave sleep.

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17. A method according to claim 1 wherein the compound of formula I that is administered is pregabalin.

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18. A method according to claim 2 wherein the compound of formula I that is administered is pregabalin.

- 19. A method according to claim 3 wherein the compound of formula I that is administered is pregabalin.
- 20. A method according to claim 4 wherein the compound of formula I that is administered is pregabalin.
 - 21. A method according to claim 5 wherein the compound of formula I that is administered is pregabalin.
- 10 22. A method according to claim 6 wherein the compound of formula I that is administered is pregabalin.
 - 23. A method according to claim 7 wherein the compound of formula I that is administered is pregabalin.
 - 24. A method according to claim 8 wherein the compound of formula I that is administered is pregabalin.
- 25. A method according to claim 11 wherein the compound of formula I that is administered is pregabalin.
 - 26. A method according to claim 16 wherein the compound of formula I that is administered is pregabalin.
- 27. A method according to claim 17 wherein the compound of formula I that is administered is pregabalin.

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